REMARKS

The Amendment, filed in response to the Office Action mailed September 12, 2008, is believed to be fully responsive to all issues raised in the Action. A favorable reconsideration of the application is respectfully requested.

Claims 1 and 3-13 are all the claims pending in the instant application. Claims 1 and 4-12 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b). Claim 3 is rejected and objected to. Upon entry of this Amendment, which is respectfully requested, Claim 3 will be amended and new claim 13, which refers to claim 3, is added.

Support for the amendment to Claim 3 can be found throughout the specification, at least at page 4, paragraph [0087], at page 5 paragraphs [0094]-[0097], at page 6, paragraphs [0103]-[0108] of the published application (US2007/0218031 A1). Support for new Claim 13 can be found throughout the specification, for example, at page 6, paragraphs [0130]-[0108] and original Claim 3.

Response to Claim Objections

In the Office Action, Claim 3 is objected to because the term "to form" in Claim 3 is repeated one after the other. The Office Action also states that the step reciting the immunoprecipitation assay in Claim 3 is indecipherable and thus the Examiner requests further clarification.

In response, Claim 3 has been amended to correct the typographical error.

Additionally, Claim 3 has been further amended to recite more concisely the immunoprecipitation steps examining the level of AICD/p53 complex in neurons, rendering the objection moot. Accordingly, withdrawal of the objection is respectfully requested.

Response to Claim Rejections - 35 U.S.C. § 112

In the Office Action, Claim 3 is rejected under 35 U.S.C. § 112, second paragraph for the following reasons.

1. The Examiner states that amended Claim 3 is indecipherable for the same reason as described in the Examiner's objection to Claim 3.

This rejection has been addressed by the amendment made to Claim 3 in response to the Examiner's objection to Claim 3.

2. The Office Action states that Claim 3 is also incomplete for omitting the following essential steps: (1) the active steps by which the drug is developed as a drug for the prevention and/or treatment of Alzheimer's disease, (2) the active step by which AICD and p53 are "in the presence of cisplatin" and (3) the step by which the second and third immune complexes are formed.

With regard to step (1), the Examiner requests Applicant either to recite the active steps by which the drug is developed or limit the scope of Claim 3 as recited in the preamble.

In response, without conceding or commenting on the merits of the rejection, solely to advance prosecution of the present application, Claim 3 has been amended to remove "candidate drug for development of a drug for the prevention and/or treatment of Alzheimer's disease." Claim 3 has been further amended to recite the limitation only directed to screening a compound that inhibits binding of AICD and p53 as shown in step (f) of Claim 3.

With respect to step (2), the Examiner states that it is not clear if the step reciting the cisplatin requires co-expression or endogenous expression. The Examiner also states that it is not clear how the element is related to the requirements of the method.

In response, Applicant notes that cisplatin is a platinum-based chemical compound that crosslinks DNA and thus induce cell death as described in the specification. (See page 4, paragraphs [0082-0087]). Accordingly, Applicant submits that cisplatin does not require expression. Further, the instant specification discloses that adding cisplatin in neuroblastoma cell line (SH-SY5Y) increases the endogenous p53 level and its interaction with β-APP-derived peptide. (See page 4, paragraph [0087]). Thus, Applicant submits that the purpose of adding cisplatin in culture is to enhance the interaction between the p53 and AICD via increasing the stability/activity of p53.

In order to clarify the method step, Claim 3 has been further amended to recite "culturing neurons.....in a culture medium that is supplemented with cisplatin,....." as shown in step (a) in Claim 3.

With regard to step (3), Applicant submits that this rejection has been addressed by the amendment made to Claim 3 in response to the Examiner's objection to Claim 3.

Thus, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

3. The Examiner states that the term "inhibit" recited in Claim 3 is indefinite for its recitation of a relative term. The Examiner asserts that the term "inhibit" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree. The Examiner states that absent such recitation one of ordinary skill in the art would not be reasonably apprised as to the point of reference for inhibition of an interaction between AICD and p53.

In response, Applicant submits that the rejection is overcome for the following reasons. Applicant submits that the term "inhibit" is well defined in the specification. Specifically, the instant specification indicates that the effect of the candidate drug on the interaction between two molecules can be measured by immunoprecipitation with an antibody to one of the two molecules and by subsequent detection/quantification of the other molecule contained in the precipitate using an immunological technique (immunoblotting or the like). (See page 6, paragraphs [0108-0109]). Thus, Applicant submits that the inhibiting effect of the candidate drug on the interaction between AICD and p53 can be ascertained from the recited measuring methods.

In order to clarify the above point, Claim 3 has been amended to recite the presence and absence of a candidate drug in culture (step (a)), a comparing step (step (e)) and a selecting step (step (e)). Accordingly, the Examiner is requested, respectfully, to reconsider and remove this rejection under 35 U.S.C. § 112, second paragraph.

5. In the Office Action, the Examiner states that the term "small" in Claim 3 is also a relative term and thus indefinite. The Examiner states that the term "small" is not defined by the claim and the specification.

In response, Applicant notes that the instant specification indicates that the effect of the candidate drug on the interaction between AICD and p53 can be measured with an antibody to one of the two molecules which can detect and quantify the other molecule contained in the precipitate using an immunological technique. Thus, the candidate compound can be screened for by adding a compound to the culture system, and comparing the AICD/p53 complex with the complex prepared from cells which do not contain the compound. Therefore, the recitation of

"small compared to" relates detection/quantification based on the AICD/p53 complex of the culture containing the candidate compound to the immunoprecipitate which does not contain the drug, and thereby provides a standard for ascertaining the requisite degree.

In order to clarify the above point, Claim 3 has been amended to recite a comparing step (step (e)) and a selecting step (step (e)). Accordingly, the Examiner is requested, respectfully, to reconsider and remove this rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 101

In the Office Action, Claim 3 is rejected under 35 U.S.C. § 101. The Office Action states that the claimed invention allegedly lacks patentable utility.

The Office Action states that the invention, drawn to a screening method wherein a drug that inhibits the interaction between AICD and p53 is selected for further development of a drug for the prevention/treatment of Alzheimer's disease, is not supported by either a specific and substantial asserted utility or a well established utility. Specifically, the Examiner states that asserted function of the AICD and p53 in Alzheimer's disease is purely hypothetical based upon a putative interaction between the APP intracellular C-terminal domains and p53 (Specification Figure 1). Further, the Examiner asserts that with regard to the asserted utilities of the claimed invention, there is no example a real world use for which the method may be used to develop an Alzheimer's disease; and the specification only states that general methods may be practiced for further development or further study of a drug that may have the potential for treatment/prevention of Alzheimer's disease.

In response, Applicant submits that the rejection is overcome for the following reasons. Initially, Applicant notes that Claim 3 is directed to screening a compound that inhibits the interaction between AICD and p53 in neurons. The instant specification indicates that AICD, which is produced on the C-terminal side, localizes to the nucleus, interacts with p53 in the nucleus, enhancing the stability of p53, and that this increases the transcription factor activity, and unique activities of p53 such as cell proliferation-suppressing activity and cell death-inducing activity, and thereby induces neuronal death. Therefore, the interaction between AICD and p53 is involved in the onset of Alzheimer's disease. (See page 5, paragraph [0096]).

Furthermore, Applicant notes that the involvement of β-APP in the pathogenesis of Alzheimer's disease is well established in the art. As disclosed in the specification (See paragraph [0097]), many efforts have been made in discovering a compound that can inhibit the cleavage of APP (e.g., β- or γ-Secretase inhibitors) in order to find a potential drug that can treat the Alzheimer's disease. Applicant also notes that, however, recent attempts to immunize a subject with a vaccine against the N-terminal fragments of β-APP (β- 42, β- 40) was partly unsuccessful in repairing damaged neurons though it showed promising effects on clearing extracellular amyloid plaques in the brain. Thus, it is imperative to find a drug that not only can clear amyloid plaques, but also can prevent neuronal cell death in the affected brain. In this regard, p53-mediated apoptosis in neurons facilitated by AICD-p53 interaction as disclosed in the specification could be a key mechanism in inducing cell death in neurons affected by Alzheimer's disease. Accordingly, the compound that can inhibit the AICD-p53 interaction and prevent neuronal cell death is able to treat neurons from apoptosis in the affected brain, and thus Applicant submits that Claim 3 meets the utility requirement.

For the reasons set forth above, Applicant disagrees with the Examiner on this rejection. Nevertheless, solely to advance prosecution of the present application, Claim 3 has been amended to recite a screening method only directed to screening a compound that inhibits the binding between AICD and p53 without reciting the compound's functional link to treating Alzheimer's disease.

Accordingly, the Examiner is requested, respectfully, to reconsider and remove the 35 U.S.C. § 101 rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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